



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Supplemental Evidence and Data Request on Interventional Treatments for Acute and Chronic Pain: Systematic Review

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for Supplemental Evidence and Data Submissions

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Interventional Treatments for Acute and Chronic Pain: Systematic Review*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

**DATES:** *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

#### ADDRESSES:

*E-mail submissions:* [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov)

*Print submissions:*

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

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**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Interventional Treatments for Acute and Chronic Pain: Systematic Review*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Interventional Treatments for Acute and Chronic Pain*, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/interventional-treatments-pain/protocol>

This is to notify the public that the EPC Program would find the following information on *Interventional Treatments for Acute and Chronic Pain* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
  - *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*

- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

*The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.*

## **Key Questions (KQs)**

KQ1: What are the effectiveness and harms of selected interventional procedures (vertebral augmentation procedures, piriformis injection, sphenopalatine block, occipital nerve stimulation, cooled or pulsed radiofrequency ablation, intradiscal and facet joint platelet rich plasma, intradiscal methylene blue, intradiscal ozone, and peripheral nerve stimulation) versus placebo, a sham procedure, or no interventional procedure for Medicare beneficiaries with pain?

- a. How do the effectiveness and harms vary according to demographic (age, sex, race/ethnicity), clinical (type of pain, severity of pain, prior treatments, medical and psychiatric co-morbidities), and technical factors (variations in techniques, intensity, frequency, dose, and number of treatments)?

## **PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)**

<b>PICOTS</b>	<b>Inclusion</b>	<b>Exclusion</b>
<b>Population</b>	<p>Adults with pain of any duration (pain conditions for each interventional procedure specified below); will highlight studies of populations applicable to Medicare, defined as persons enrolled in Medicare, age &gt;55 years, or persons with disability (including end-stage renal disease [ESRD]), if available</p> <p>Population subgroups of interest include those based on demographics (age, sex, race/ethnicity) and clinical factors (type of pain, severity of pain, prior treatments, medical and psychiatric co-morbidities, including presence of disability [including ESRD], prior substance use disorder, and psychological co-morbidities)</p>	<ul style="list-style-type: none"><li>• Patients undergoing end-of-life care, terminally ill (e.g., hospice) patients; those under supervised palliative care; those with pain due to metastatic or advanced cancer</li><li>• Children</li></ul>

PICOTS	Inclusion	Exclusion
<b>Intervention</b>	<p>1) Vertebral augmentation procedures (vertebroplasty and kyphoplasty) for pain due to vertebral compression fracture</p> <p>2) Piriformis injection (local anesthetic, corticosteroid, and/or botulinum toxin) for piriformis syndrome</p> <p>3) Sphenopalatine block for trigeminal neuralgia or headache</p> <p>4) Occipital stimulation for headache</p> <p>5) Cooled radiofrequency denervation for degenerative back or hip pain and pulsed radiofrequency denervation for degenerative back pain</p> <p>6) Intradiscal and facet joint platelet rich plasma for presumed discogenic back pain</p> <p>7) Intradiscal stem cells for presumed discogenic back pain</p> <p>8) Intradiscal methylene blue for presumed discogenic back pain</p> <p>9) Intradiscal ozone for radicular low back pain or non-radicular, presumed discogenic back pain</p> <p>10) Peripheral nerve stimulation for ulnar, median, or radial neuropathy</p> <p>Technical factors of interest as potential modifiers of treatment effect include variations in techniques, intensity, frequency, dose, or number of treatments.</p>	<ul style="list-style-type: none"> <li>• Minimally invasive surgical procedures</li> <li>• Orthopedic intra-articular and soft tissue injections</li> <li>• Local soft tissue injections</li> <li>• Other interventional procedures and conditions not listed as included</li> </ul>
<b>Comparator</b>	<p>Placebo, sham interventional procedure, or no interventional procedure</p> <p>For cooled and pulsed radiofrequency denervation: standard (thermal, continuous) radiofrequency denervation</p>	<p>Active treatments, other than standard radiofrequency denervation as a comparison for cooled radiofrequency denervation</p>
<b>Outcome</b>	<ul style="list-style-type: none"> <li>• <b>Primary:</b> Pain, function</li> <li>• <b>Secondary:</b> HRQOL, emotional function (e.g., depression, anxiety), opioid use, surgery rates</li> <li>• Global improvement</li> <li>• Harms (e.g., bleeding, infection, other complications), adverse events, unintended consequences</li> </ul>	<p><b>Patient-oriented outcomes</b></p> <ul style="list-style-type: none"> <li>• Non-validated instruments for outcomes (e.g., pain, function, HRQOL, depression, etc.)</li> <li>• Intermediate outcomes (e.g., range of motion, physical strength, etc.)</li> </ul>

<b>PICOTS</b>	<b>Inclusion</b>	<b>Exclusion</b>
<b>Timing</b>	Duration of followup: $\geq 1$ month; categorized as short term (1 to $<6$ months), intermediate term ( $\geq 6$ to $<12$ months) and long term ( $\geq 12$ months) following intervention	$<1$ month
<b>Setting</b>	Any	None
<b>Study design, publication type</b>	Randomized clinical trials and cohort studies if RCTs are not available Large ( $n > 500$ ) case series for serious, rare harms	<ul style="list-style-type: none"> <li>• Case reports</li> <li>• Case series (other than large case series for serious, rare harms)</li> <li>• Case-control studies, cross-sectional studies</li> <li>• Conference proceedings, editorials, letters, white papers, citations that have not been peer-reviewed</li> </ul>

**Marquita Cullom,**

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